

71847-2

8/5/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 5 2013

Mr. Levi Howell
Medentech Ltd.
c/o Clearon Corporation
95 MacCorkle Avenue S.W.
South Charleston, WV 25303

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: KLOR-KLEEN
EPA Reg.#: 71847-2
Application Date: May 31, 2013
Receipt Date: June 04, 2013

Dear Mr. Howell:

This acknowledges the receipt of your Amendment application dated May 31, 2013 in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.

Proposed Amendment:

Amend by adding administrative directions, reformatted the Directions for Use, correct grammatical/spelling errors and various minor other changes for KLOR-KLEEN product label (EPA Reg#71847-5). The proposed label dated May 24, 2013 (pin punch 05/29/13) was updated on July 24, 2013 (pin punch 07/24/13).


General Comment:

Based on the review of the material submitted, the label amendment for Inovotabs® product label (EPA Reg#71847-3) is **acceptable**.

A copy of the accepted stamped label is enclosed for your record. Submit one copy of your final printed label/labeling before distributing or selling the product bearing the revised label/labeling. This amendment, a stamped label with comment, and a copy of this letter have been inserted in your file for future reference.

If you have any questions or comments concerning this letter, please contact David Liem by email at liem.david@epa.gov or call (703) 305-1284.

Sincerely,


Demson Fuller
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Att: Accepted Stamped Label

{71847-2}

{KLOR-KLEEN™ Master Label Ver.10}

{DOA: 07242013}

{All text in brackets [xxx] is optional and may or may not be intended on a final label.}
{All text in braces {xxx} is administrative and will not appear on a final label.}

KLOR-KLEEN™

[Effervescent Disinfectant Tablets for Hospitals and Institutional Use.]

[KLOR-KLEEN™ is effective against the following micro-organisms on pre-cleaned, hard, nonporous, inanimate surfaces: Salmonella enterica, Staphylococcus aureus, Pseudomonas aeruginosa, Klebsiella pneumoniae, Staphylococcus epidermidis, Escherichia coli O157:H7, Staphylococcus aureus - MRSA & GRSA, Poliovirus type 1, Herpes simplex virus type 1, Hepatitis A virus, Human Immunodeficiency Virus Type 1 (associated with AIDS) or (AIDS Virus), Canine Parvovirus, Newcastle Disease Virus, Pseudorabies, Canine Distemper Virus, Feline Calicivirus, Norovirus, Enterococcus faecalis Vancomycin Resistant, and Trichophyton mentagrophytes.]

[KLOR-KLEEN™ is designed to provide effective cleaning, deodorizing and disinfection in areas where it is of prime importance in controlling the hazard of cross contamination on treated pre-cleaned, hard, nonporous, inanimate surfaces.]

[KLOR-KLEEN™ is for use in:

- Hospitals, nursing homes, medical and dental offices and clinics, operating rooms, isolation wards, and medical research facilities.
- Day care centers and nurseries.
- Veterinary clinics, animal life science laboratories, kennels, breeding and grooming establishments, pet animal quarters, zoos, pet shops, and other animal care facilities.]

[KLOR-KLEEN™ is a disinfectant and cleaner that disinfects, cleans and deodorizes pre-cleaned, hard, nonporous, inanimate surfaces. This pre-cleaning may be accomplished with any cleaning solution including Klor-Kleen.]

[KLOR-KLEEN™ provides effective cleaning strength that will not dull high gloss floor finishes with repeated use.]

Active Ingredient:

Sodium Dichloroisocyanurate.....48.21%

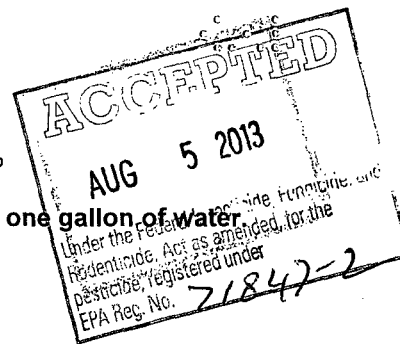
Other Ingredients:.....51.79%

Total:.....100.00%

Each tablet will produce a 937 ppm disinfectant solution when dissolved in one gallon of water.

KEEP OUT OF REACH OF CHILDREN

DANGER



FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF INHALED	<ul style="list-style-type: none">• Move person to fresh air

{71847-2}

{KLOR-KLEEN™ Master Label Ver.10}

{DOA: 07242013}

	<ul style="list-style-type: none"> If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
<p>Have the product container or label with you when calling a poison control center or doctor, or when going for treatment.</p> <p>YOU MAY ALSO CONTACT [1-800-420-9236] FOR EMERGENCY MEDICAL TREATMENT INFORMATION.</p>	
<p>NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

See [back][side] panel[s] for additional precautionary statements [and first aid].

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes irreversible eye damage. Harmful if swallowed, inhaled, or absorbed through skin.

Do not get in eyes, on skin, or on clothing. Avoid breathing dust. Wear chemical-resistant gloves and protective eyewear (safety glasses or face shield) when making up solution. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

{For end-use products packaged in containers with sizes of less than 50 pounds.}

[This product is toxic to fish and aquatic organisms.]

{For end-use products packaged in containers with sizes of greater than or equal to 50 pounds.}

[This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read entire label and use strictly in accordance with precautionary statements and directions.

[This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or, (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.]

[PREPARATION OF USE SOLUTION:

Add 1 KLOR-KLEEN tablet to 1 gallon of water (77°F/25°C) to obtain a concentration of 937 ppm (mg/Litre) of available chlorine. This solution should be freshly prepared. Use within one day. Keep in a properly labeled container to protect against contamination. Unused solution should be discarded.]

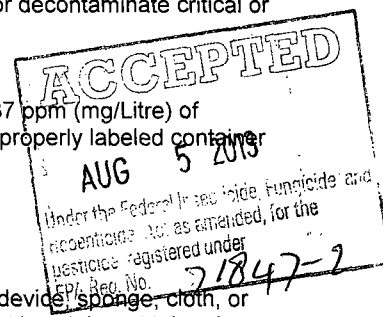
[KLOR-KLEEN is a Hospital Use Disinfectant at 1 tablet per gallon.]

[Disinfection/Virucidal Directions:

Apply use solution to pre-cleaned, hard, non-porous, inanimate surfaces with brush, spray device, sponge, cloth, or mop to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove product by wiping with brush, sponge, or cloth. For sprayer applications use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge, or cloth. Do not breathe spray mist.

Before using this product, food products and packaging materials must be removed from the room or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with potable water.

Prepare a fresh solution daily or when use dilution becomes diluted or soiled.]



{71847-2}

{KLOR-KLEEN™ Master Label Ver.10}

{DOA: 07242013}

[Kills HIV-1 on PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).]

[SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of Klor-Kleen™. This pre-cleaning may be accomplished with any cleaning solution including Klor-Kleen™.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

CONTACT TIME: Leave surfaces wet for 10 minutes.]

[ANIMAL PATHOGENS:

When used at one tablet per gallon of water, applied as outlined under Disinfection/Virucidal Directions, Klor-Kleen is effective against the following animal pathogens: *Feline Calicivirus*, *Norovirus*, *Canine Distemper virus*, *Infectious Canine hepatitis*, *Teschen/Talfan disease*, *Avian influenza*, *Porcine parvovirus*, *Runting & Stinging virus (tenosynovitis)*, *Actinobacillus pleuropneumoniae*, *Bordetella bronchiseptica*, (rhinitis), *Brachyspira* (Treponema/Serpulina) *hyodysenteriae* (swine dysentery), *Gumboro disease*, *Streptococcus uberis*, *Streptococcus dysgalactiae*, and *Clostridium perfringens* USDA with a 10 minute contact time. For *Transmissible gastroenteritis (TGE)*, *Swine Vesicular disease*, *African swine fever*, *Hog cholera/Classical swine fever*, and *Avipox (fowl pox)*, a 30 minute contact time is required. Re-apply product as necessary to ensure surface remains wet.]

STORAGE AND DISPOSAL

Do not contaminate food or feed by storage or disposal.

Pesticide Storage

Keep this product dry in a tightly sealed container when not in use. Store in cool, dry, well ventilated area away from heat or open flame. In case of decomposition, isolate container (if possible) and flood area with large amounts of water to dissolve all material before discarding the container.

Pesticide Disposal

Pesticide waste may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If the waste cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest Regional Office for guidance.

Container Handling [and Disposal]

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[WARRANTY

Seller warrants that this product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with label directions under normal conditions of use, but to the extent consistent with applicable law, neither this warranty nor any other warranty of MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, expressed or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller, and Buyer assumes the risk of any such use.]

Manufactured by:

Medentech Ltd.
Whitemill Industrial Estate, Clonard Road
Wexford, Ireland

EPA Reg. No. 71847-2

EPA Est. No. _____

[Material][Label] No. _____

